DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

Orthofix Srl
% Ms. Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
P.O. Box 15729
Wilmington, North Carolina 28408

Re: K142052
Trade/Device Name: Orthofix Galaxy UNYCO Diaphyseal Tibia Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: November 3, 2014
Received: November 4, 2014

Dear Ms. Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142052

Device Name
Galaxy UNYCO Diaphyseal Tibia Kit

Indications for Use *(Describe)*
The Galaxy UNYCO Diaphyseal Tibia Kit is intended to be used to provide treatment for bone stabilization in trauma, specifically lower limb fractures that require temporary fixation prior to definitive fixation.
The Galaxy UNYCO Diaphyseal Tibia Kit is indicated to be used for temporary stabilization of tibial fractures in trauma procedures (damage control orthopaedics prior to definitive treatment). The product is indicated for non-weight- bearing use. The indications for use include:
• Tibial fractures extending from about 8cm below the knee to about 7 cm above the ankle joint, including comminuted open or closed tibial fractures and polytrauma.
• Temporary stabilisation of the tibia after debridement for osteomyelitis or an infected non-union pending second stage treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Premarket Notification
Orthofix Galaxy UNYCO Diaphyseal Tibia Kit

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
	Via delle Nazioni, 9 | 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380

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Fax	+ 39 045 6719.380
email	gianlucaricadona@orthofix.com
Date Prepared	November 28th, 2014

Trade Name	Orthofix Galaxy UNYCO Diaphyseal Tibia Kit
Common Name	External Fixation Device and Accessories
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories.
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	KTT

Device Name	**510(k) Number**	**Manufacturer**
Synthes Large External Fixation, MR Conditional	K082650	Synthes
Orthofix Galaxy Fixation	K113770	Orthofix Srl
Hoffmann 3 External Fixation System	K122284	Stryker

Description	The Orthofix Galaxy UNYCO Diaphyseal Tibia Kit consists of a series of UNYCO Screws, UNYCO Cancellous Screws, Large Multiscrew Clamp for UNYCO Screws, Rods ∅12mm L 350mm and specific application tools. External fixation systems are modular, therefore different frame configurations are possible. The Orthofix components in the Galaxy UNYCO Diaphyseal Tibia Kit are not intended to replace normal healthy bone or to withstand the stresses of weight bearing. The System is intended to be used to provide treatment for bone stabilization in trauma, specifically lower limb fractures that require temporary fixation prior to definitive fixation. The System may be used in conjunction with the Orthofix Galaxy Fixation system for crossing the knee and the ankle during temporary fixation.

Indications and Intended Use	The Galaxy UNYCO Diaphyseal Tibia Kit is intended to be used to provide treatment for bone stabilization in trauma, specifically lower limb fractures that require temporary fixation prior to definitive fixation. The Galaxy UNYCO Diaphyseal Tibia Kit is indicated to be used for

	temporary stabilization of tibial fractures in trauma procedures (damage control orthopaedics prior to definitive treatment). The product is indicated for non-weight- bearing use. The indications for use include: • Tibial fractures extending from about 8cm below the knee to about 7 cm above the ankle joint, including comminuted open or closed tibial fractures and polytrauma. • Temporary stabilisation of the tibia after debridement for osteomyelitis or an infected non□union pending second stage treatment.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Orthofix Galaxy UNYCO Diaphyseal Tibia Kit is substantially equivalent to the legally marketed Predicates. The devices and accessories included in the Orthofix Galaxy UNYCO Diaphyseal Tibia Kit and the predicate devices are all external fracture fixation systems as defined in 21 CFR 888.3030. The Galaxy UNYCO Diaphyseal Tibia Kit is substantially equivalent to the predicate devices in intended use, site of application, patient population, conditions-of-use, mechanical performances, basic design, operating principles, and materials. The Galaxy UNYCO Diaphyseal Tibia Kit is comparable to its predicate in size and materials. Testing in accordance with ASTM F 1541-02 shows the mechanical strength of the subject device to be at least equivalent to the predicate devices.

Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicates. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following mechanical testing was performed: • ASTM F 1541 “Standard Specification and Test Methods for External Skeletal Fixation Devices” MRI compatibility testing was also conducted per: • ASTM F2182 “Standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging”

Conclusion	Based on design, materials, intended use, technological characteristics, and comparison to predicate devices, the Subject Orthofix Galaxy UNYCO Diaphyseal Tibia Kit has been shown to be substantially equivalent to legally marketed predicate devices.